

receptor, an isolated nucleic acid molecule comprising SEQ ID NO:3, an isolated nucleic acid molecule encoding SEQ ID NO:4, vectors encoding SEQ ID NOs: 3 and 4, cells containing SEQ ID NOs: 3 and 4 and methods of producing a hemopoietin receptor.

#### REMARKS

Claims 1-35 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 as follows:

I. Claims 1-6 and 7, drawn to isolated nucleic acid molecule encoding an hemopoietin receptor, isolated nucleic acid molecule comprising SEQ ID NO:1, isolated nucleic acid molecule encoding SEQ ID NO:2, vectors encoding, cells containing the aforementioned expression vectors and method of producing the protein.

II. Claims 1-10, 25 and 28-30, drawn to isolated nucleic acid molecule encoding an hemopoietin receptor, isolated nucleic acid molecule comprising SEQ ID NO:3, isolated nucleic acid molecule encoding SEQ ID NO:4, vectors encoding, cells containing the aforementioned expression vectors and method of producing the protein.

III. Claims 11-17 and 24 drawn to recombinant polypeptide comprising SEQ ID NO:2 or encoded by SEQ ID NO:1.

IV. Claims 11-17 and 24 drawn to recombinant polypeptides comprising SEQ ID NO:3 or encoded by SEQ ID NO:4.

V. Claims 18-19, drawn to an antibody which binds to recombinant polypeptide comprising SEQ ID NO:2 or encoded by SEQ ID NO:1.

VI. Claims 18-19, drawn to an antibody which binds to recombinant polypeptide comprising SEQ ID NO:4 or encoded by SEQ ID NO:3.

VII. Claim 20, drawn to a hybrid hemopoietin receptor capable of interaction with at least two cytokine, said hybrid containing all or

part of the amino acid sequence set forth in SEQ ID NO:2.

VIII. Claim 20, drawn to a hybrid hemopoietin receptor capable of interaction with at least two cytokine, said hybrid containing all or part of the amino acid sequence set forth in SEQ ID NO:4.

IX. Claims 21, 23 drawn to a hybrid hemopoietin receptor capable of interaction with at least one cytokine, said hybrid containing all or part of the amino acid sequence set forth in SEQ ID NO:2.

X. Claims 21, 23 drawn to a hybrid hemopoietin receptor capable of interaction with at least one cytokine, said hybrid containing all or part of the amino acid sequence set forth in SEQ ID NO:4.

XI. Claim 20, drawn to a hybrid hemopoietin receptor capable of interaction IL4.

XII. Claim 26, drawn to a method of treatment using the recombinant protein of Group III.

XIII. Claim 26, drawn to a method of treatment using the recombinant protein of Group IV.

XIV. Claim 27, drawn to a method of treating asthma using the recombinant protein of Group III.

XV. Claim 27, drawn to a method of treating asthma using the recombinant protein of Group IV.

XVI. Claims 31-32 drawn to a chimeric protein comprising a first portion capable of interaction with IL-13 and a second portion with haemopoietin receptor, receptor tyrosine kinase, TNF/NGF receptor or a G protein receptor.

XVII. Claims 33 and 35, drawn to a method of monitoring the level of IL-4.

XVIII. Claims 34 and 35, drawn to a method of monitoring the level of IL-3.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents eighteen separate and distinct inventions. The Examiner has specifically alleged that "the inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features." The Examiner has further alleged that "the inventions of Groups II-XVII are drawn to products having materially different structures and function...".

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group II, Claims 1-10, 25 and 28-30, directed to isolated nucleic acid molecules encoding a hemopoietin receptor, isolated nucleic acid molecules comprising SEQ ID NOs: 3 and 4, vectors encoding SEQ ID NOs: 3 and 4, cells containing SEQ ID NOs: 3 and 4, and methods of producing the hemopoietin receptor.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules

governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." (Emphasis added.)

Applicants submit that Groups I-XVIII are not distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application.

Group IV, Claims 11-17 and 24 is directed to a recombinant polypeptide comprising SEQ ID NOS: 3 and 4 which [SEQ ID NOS.] correspond to the isolated nucleic acids encoding the hemopoietin receptor of Group II. Group VI, Claims 18-19 are drawn to an antibody which binds to the recombinant polypeptide of Group IV. Groups VIII and X, Claims 20, 21 and 23, are drawn to hybrid hemopoietin receptors containing all or part of the amino acid sequence of SEQ ID NO:4 of Group IV. Groups XIII and XV, Claims 26 and 27, are drawn to methods of treatment using the recombinant protein of Group IV.

PCT Rule 13.2 defines claims of different categories permitted by Rule 13.1. One permissible combination is as follows:

- (I) In addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process

specially adapted for the manufacture of the said product, and the inclusion in the same international application of an independent claim for the use of said product. (Emphasis added.)

In the present circumstances, the product of Groups II and IV are specifically employed in the method of Groups XIII and XV. Accordingly, at least Groups II, IV, XII and XV should be examined in a single application.

Moreover, the product of Groups I-XI and XVI can be employed in the process of Groups XII-XV and XVII-XVIII. Thus, the claims are not separate and distinct, but interrelated and interdependent.

Furthermore, Applicants respectfully suggest that, in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive cost or the loss or compromise of the term of the related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional

applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations.

The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's

legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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